SEP 2 2 2003

K032778

Attachment 2

Belmont
Instrument Corporation

Creating a New Standard of Care

Registered in Accordance with ISO-9001 and EN 46001

PREMARKET NOTIFICATION
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
[As Required By 21 CFR 807.92(c)]

Date prepared: September 4, 2003

1. Submitter & Manufacturing Site: Belmont Instrument Corporation
780 Boston Road
Billerica, MA 01821

Establishment Registration Number: 1219702

2. Contact Person: Uraiwan P. Labadini, Quality Assurance/Regulatory Affairs Manager

Telephone: (978) 663-0212 Ext. 28 Fax: (978) 663-0214

3. Trade Name: The Belmont Fluid Management System (*FMS2000*)

4. Common name: Infusion Pump with Warmer.

5. Classification name: Infusion Pump (per 21 CFR section 880.5725)

6. Product Code: 80 FRN Infusion Pump
Device Class: Class II

7. Performance Standards:

No performance standards have been officially adopted by the F.D.A.

8. The Modified Belmont Fluid Management Disposable Set System is substantially equivalent to the Belmont Fluid Management Disposable Set System, which was the subject of Premarket Notification #K972284 submitted in June 1997 and the accessory kits received F.D.A 510(k) concurrence to market in August 1999, 510(k) #K992672.

9. Brief Description of the *FMS2000* Device (Unchanged by the Modification): The Belmont Fluid Management System (*FMS2000*) combines advanced microprocessor technology with an efficient mechanical system to provide a high speed, simple and safe system for rapid infusion of warmed fluid. The Belmont *FMS2000* infuses blood, replacement IV fluids or irrigation fluids warmed to physiologic temperature at user-set rates from 10 to 500 milliliters per minute (ml/min). A low infusion rate at 2.5 ml/min (150 ml/hr) is also available without heating.

   The system monitors temperature, line pressure, and air in the fluid path to ensure safe operation and alarms at all unsafe conditions. A hardware override circuit prevents unsafe operation in case of system computer failure. A touch screen displays flow rate, total fluid infused, temperature, line pressure, alarm and status messages and proper procedures to proceed safely after an alarm situation.

   A battery backup allows for mobile transport of the patient and system. During battery operation, fluid warming is disabled while pump operation and safety monitoring remain active.

   The new reservoir, our own design, will be used instead of Gish Biomedical Inc, reservoir. The reservoir is used for convenience in infusing large volumes of fluid (rather than having to change individual bags.) Tubing and fittings are added, same as the existing reservoir, to be used with our current disposable set.

10. Intended Use (Unchanged by the Modification): The Belmont *FMS2000* is for use in high blood loss surgical procedures, trauma and any situation where rapid replacement of warmed blood or replacement fluid at 10 -500 ml/min is required. It can also be used to deliver irrigation fluids at rates up to 500 ml/min. The reservoir is used to increase the fluid supply capacity of the Belmont instrument *FMS2000* 3-Spike disposable Set.

11. Summary of the technological characteristics of the Modifies Belmont Disposable Set and our current Disposable Set.

    The modified Belmont disposable set and our current disposable set are similar in design and concept.

12. Summary of Nonclinical Tests and Results

In order to verify performance of the Belmont *FMS2000* in support of substantial equivalence, the following tests were carried out:

a. The ability of the system to warm cold fluids to physiological temperature over the full range of flow rate and operating conditions.

b. The ability of the system to detect and alarm at unsafe or ineffective operating conditions including operator errors, the failure of the system sensors, the failure of the system software or computer, and other internal system malfunctions.

c. The ability of the new reservoir not to damage blood.

The system was tested for hemocompatibility by testing for red cell hemolysis, and red cell fragility. The system was found to have negligible effect on anticoagulated blood. Hemolysis assessment was done using 'Sigma Diagnostics, Plasma Hemoglobin' Procedure No. 527.

13. Conclusion: The new reservoir is substantially equivalent to our current reservoir which received 510(k) approval in August 1999.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2003

Mr. Uraiwan P. Labadini
Quality Assurance Regulatory Affairs Manager
Belmont Instrument Corporation
780 Boston Road
Billerica, Massachusetts 01821

Re: K032778
Trade/Device Name: Large Volume Fluid Reservoir
Regulation Number: K032778
Regulation Name: Unclassified
Regulatory Class: II
Product Code: LGZ
Dated: September 4, 2003
Received: September 8, 2003

Dear Mr. Labadini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

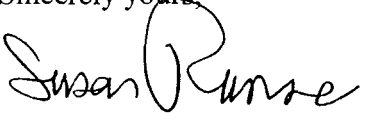
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number: K032778

Device Name: Reservoir

Indications For Use:

Intended Use of the *FMS2000* (Unchanged by the modification):

Infusion of crystalloid, colloid, or blood product, including packed red cells, as volume replacement for patients suffering from blood loss due to trauma or surgery. Infusion of warmed fluid to rewarm patients after surgery or for hypothermia. Infusion of warmed fluid for irrigation in urology purposes.

Intended Use of the reservoir (Unchanged by the modification):

The reservoir is used for convenience in infusing large volumes of fluid (rather than having to change individual bags.) Tubing and fittings are added, same as the existing reservoir, to be used with our current disposable set.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032778

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)